K033321

NOV - 5 2003

Section 9
510(k) Summary

Submitter:	NeoMetrics, Inc. 14800 28th Avenue South, Suite 150 Plymouth, MN 55447 Telephone: 763-559-4440 Fax: 763-559-7676
Contact Person:	Mark Pederson Product Development Engineer Telephone: 763-559-4440 Fax: 763-559-7676 pedersonm@qwest.net
Date Prepared:	October 14, 2003
Trade Name:	Selectiva SB Guidewire
Classification Name and Number:	Wire, Guide, Catheter 870.1330
Product Code:	DQX
Predicate Device(s):	NeoMetrics *Selectiva*™ Guidewire (K013024) FlexMedics FlexFinder Guidewire (K943390)
Device Description:	The Selectiva SB Guidewires are constructed of a nickel-titanium alloy with a PTFE polymer jacket. Devices are available in a diameter of 0.035 inches and in lengths ranging from 40 to 300 cm.
Intended Use:	The NeoMetrics Selectiva SB Guidewire is intended to facilitate the placement of devices for diagnostic and interventional procedures. NOTE: These guidewires are not intended for PTCA use.
Functional and Safety Testing:	Representative samples of the device underwent bench testing to demonstrate appropriate functional and performance characteristics compared to the predicate device(s).
Conclusion:	The NeoMetrics Selectiva SB Guidewire modified as proposed in this submission, is substantially equivalent to the predicate devices. This conclusion is based upon the similarity in design, principles of operation, materials, and performance of the modified device compared to the originally, cleared device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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NeoMetrics, Inc.
c/o Mr. Mark Pederson
Product Development Engineer
14800 28th Avenue South, Suite 150
Plymouth, MN 55447

Re: K033321
Selectiva SB Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: October 14, 2003
Received: October 21, 2003

Dear Mr. Pederson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Elisa D. Harvey Jr

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033321

Section 3
Indications for Use

The NeoMetrics Selectiva SB Guidewire is intended to facilitate the placement of devices for diagnostic and interventional procedures.
NOTE: These guidewires are not intended for PTCA use.

Prescription Use X
(Per 21 CFR 801.109)

11/4/03

Division of Cardiovascular & Respiratory Devices
510(k) Number K033321